Remarks

The present invention is directed to methods of repairing dystrophic, differentiated neural tissue, such as a damaged or diseased retina or optic nerve, in humans and other animals. In particular, the invention relates to the introduction of neural progenitor cells obtained from adult donors into a dystrophic neural tissue site of an animal recipient. These adult donor-derived neural progenitor cells can functionally and morphologically integrate into both mature and immature, dystrophic neural tissue.

By the present communication, a replacement abstract is provided on a separate sheet, as per the Examiner's request.

In addition, by the present communication, claims 1, 4-13, 18 and 21 have been amended to define Applicants' invention with greater particularity. No new matter is introduced by the subject amendments as all amended claim language is fully supported by the specification and original claims. In view of the present amendments, claims 1-25 remain pending, with claims 2, 16 and 17 withdrawn from consideration. The present status of all claims in the application is provided in the Listing of Claims presented herein beginning on page 2.

The alleged lack of unity of invention of claims 1-25 under 35 U.S.C. §§ 121 and 372, and PCT Rule 13.1 is again respectfully traversed. Contrary to the Examiner's assertion, it is respectfully submitted that the claims are all linked via a single general inventive concept, *i.e.*, the introduction of neural progenitor cells derived from an adult donor into dystrophic tissue in a recipient.

The Examiner's assertion that the " 'special technical feature' of Groups I and II is not contributed by the present invention over the prior art" is respectfully submitted to be in error. The Examiner's reliance on U.S. Patent Application Publication No. US 2002/0004039 by Reid *et al.* (hereinafter referred to as "Reid") in support of this assertion is to no avail as Reid is not relevant to the present claims. While the present claims require use of neural progenitor cells

obtained from an adult donor, Reid merely teaches that a patient's own neural progenitor cells can be induced to function in particular manners by contacting them with a polypeptide that binds the epidermal growth factor receptor.

Similarly, Gage et al. (PNAS USA 92:11879-11883 (1995)) is not relevant to the present claims. While the present claims require use of neural progenitor cells obtained from adult donors to treat dystrophic neural tissue, Gage merely evaluates the ability of adult neural progenitor cells to survive upon transplantation into the adult brain.

The request for submission of an abstract on a single sheet is acknowledged. The Examiner's attention is directed to the fact that this application is a 371 of PCT Publication No. WO 00/47238, which contains an abstract on the front page thereof. As an accommodation to the Examiner, the abstract is resubmitted herewith on a separate sheet as an attachment to this communication.

The rejection of claims 1, 3-15 and 18-25 under 35 U.S.C. § 112, 2nd paragraph, as allegedly omitting essential steps, is respectfully traversed. It is respectfully submitted to be clear that introduction of neuroprogenitor cells as contemplated by the present claims inherently ameliorate dystrophic neural tissue. In efforts to make this abundantly clear, claim 1 has been amended to indicate that introducing neural progenitor cells obtained from an adult animal donor into dystrophic neural tissue in an animal recipient thereby re-populates or rescues dystrophic tissue.

The rejection of claims 1, 3-15 and 18-25 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in use of the phrase "derived from" is respectfully traversed. The objected to terminology is respectfully submitted to be clear. However, in efforts to reduce the issues and expedite prosecution, claim 1 has been amended to recite cells "obtained from" an adult donor, making it clear that an adult donor is the source of the neural progenitor cells.

The rejection of claims 1, 3-15 and 18-25 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, is respectfully traversed. Specifically, Applicants respectfully disagree with the Examiner's assertion that the specification "does not reasonably provide enablement for a method of treating various dystrophic neural tissues in an animal recipient by introducing neural progenitor cells derived from various parts of central nervous system (CNS) of an adult animal donor via various administration routes." (See page 4, lines 19-22 of the Office Action).

Applicants further disagree with the Examiner's assertion that the specification allegedly:

> . . . fails to provide adequate guidance and evidence for how to isolate and culture neural progenitor cells from various parts of CNS of an adult animal. The specification fails to provide adequate guidance and evidence for how to use the claimed neural progenitor cells to treat numerous dystrophic neural tissues derived from various neural diseases or disorders so as to provide therapeutic effect in the animal recipient either allogeneic, syngeneic, or of different species via various administration routes.

(See page 6, lines 1-6 of the Office Action). Contrary to the Examiner's assertion, the specification provides substantial guidance with respect to each point raised above. See, for example, page 7, line 29 – page 13, line 12 of Applicant's specification, which provides substantial guidance with respect to isolating and culturing neural progenitor cells. Similarly, see page 7, lines 11-28; page 9, line 20 – page 12, line 32; page 14, line 26 – page 26, line 17; page 30, line 15 – page 32, line 17; and page 37, line 1 – page 41, line 25 of Applicants' specification for substantial guidance with respect to how to use neural progenitor cells to treat dystrophic neural tissue.

The rejection of claims 1, 3-15, and 18-25 under 35 U.S.C. § 103 as allegedly being unpatentable over Gage et al., (PNAS USA, Vol. 92, pages 11879-11883 (1995)) in view of Weiss et al. (WO 97/35605 (1997)) is respectfully traversed. Applicants' invention, as defined by claim 1, distinguishes over the applied references by requiring a method of treating dystrophic neural tissue comprising introducing neural progenitor cells obtained from an adult animal donor

into dystrophic neural tissue in an animal recipient, whereby or thereby [[this sentence will be completed with whichever concluding clause(s) we decide to add to claim 1]]. As acknowledged by the Examiner, "Gage does not teach using the prepared neural progenitor cells to treat dystrophic neural tissues, wherein the donor and recipient animals are of same species or different species." (See page 10, lines 3-4 of the Office Action).

Further reliance on Weiss is unable to cure the acknowledged deficiencies of Gage. Indeed, Weiss does not disclose or suggest introducing any cells into an animal recipient. Instead, Weiss introduces defined growth factor(s) into defined regions. If there are no progenitor cells in the brain of the recipient, the Weiss process would be ineffective.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Conclusion

In view of the above amendments and remarks, reconsideration and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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Enclosure